

Applicants: Ann Marie Rodriguez, et al.  
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REMARKS

In the October 20, 2005 Office Action, the Examiner imposed a restriction under 35 U.S.C. §121 to one of the following Groups:

- I. Claims 2-7, 9-12, 25-28, 48-54, drawn to adult non-transgenic multipotent human stem cells;
- II. Claims 2-12, 26-28, 49-54, drawn to adult multipotent human stem cells comprising at least one transgene;
- III. Claims 13-24, drawn to a method for obtaining multipotent human stem cells comprising the following steps of:
  - culturing cells from a human tissue sample, in particular, human adipose tissue,
  - selecting two cell sub-populations termed a "CA" population and "CS" population, wherein the "CA" population has an adhesion rate of less than 12 hours, and the "CS" population has an adhesion rate of more than 12 hours,
  - enriching the "CA" population until a quiescent cell population is obtained, and
  - inducing proliferation of stem cells of the "CA" population, and the stems cells obtained by said method.
- IV. Claims 29-32, drawn to a use of adult multipotent human

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stem cells for *in vivo* tissue regeneration;

- V. Claims 33-37, drawn to a method of making mesodermal cells;
- VI. Claims 38-45, drawn to a screening method to identify agents that modulate differentiation of cells into cells of mesodermal lineage; and
- VII. Claims 46, 47, drawn to use of adult multipotent human stem cells in cosmetics and a cosmetic composition comprising a plurality of cells.

In addition, as indicated on page 5 of the enclosed Office Action, a species election is required as follows:

- a) Claim 29 of Group IV is generic for regeneration of tissue types: bone, adipose, muscle, or endothelial. One tissue type must be elected;
- b) Claims 33 and 34 of Group V are generic for a method of producing differentiated cells of the mesodermal lineage: adipocytes, osteoblasts, myocytes, or angiogenic. One cell of the mesodermal lineage must be selected; and
- c) Claim 38 of Group VI is generic for a screening method that identify agents that modulate or inhibit differentiation of stem cells into the mesodermal lineage: adipocytes, osteoblasts, myocytes, and inhibition of differentiation. Either one type of mesodermal lineage or

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inhibition of differentiation must be selected. Further, should the adipocyte lineage be elected (claim 39), a further election of activity in adipocytes must be selected. These activities are drawn to lipolytic, anti-lipolytic, or insulin-sensitizing activity.

The Examiner stated that claims 29, 33, 34, 38, and 39 are generic.

For the reasons set forth in the October 20, 2005 Office Action, the Examiner alleged that these inventions are distinct, and have acquired a separate status in the art because of their alleged divergent subject matter, and that restriction for examination purposes as indicated is proper.

In the October 20, 2005 Office Action, the Examiner alleged that inventions of Groups I and II are patentably distinct. The Examiner stated that the invention of Group I is drawn to adult non-transgenic multipotent human stem cells, while the invention of Group II is drawn to adult transgenic multipotent human stem cells comprising at least one transgene. The Examiner stated that the cells of the inventions of Groups I and II are allegedly structurally different from each other. The Examiner stated that the searches for the inventions of Groups I and II are burdensome because the searches are not coextensive.

The Examiner conceded that the inventions of Groups I, II and III are related as process of making and product made. The Examiner stated that these inventions are distinct if either or both of

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the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). The Examiner alleged that in the instant case while the multipotent human stem cells of the inventions of Groups I and II can be made by the method of the invention of Group III, multipotent human stem cells can be obtained by other methods. For example, stromal cells can be isolated from bone marrow.

The Examiner conceded that the inventions Groups I, II and IV/V/VI/VII are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner stated that in the instant case, the cells of the inventions of Groups I and II can be used in many, different methods, as described in the inventions of Groups IV, V, VI and VII. The Examiner stated that each method requires method steps that are distinct and different from other methods.

The Examiner alleged that the inventions of Groups III and IV/V/VI/VII are patentably distinct. The Examiner stated that the invention of Group III is drawn to a method of producing multipotent human stem cells, while the inventions of Groups IV/V/VI/VII are drawn to methods of using the multipotent human

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stem cells. The Examiner stated that while the multipotent stem cells are a common factor in these methods, each of the methods in each of these inventions requires different method steps and results in products that are structurally different from each other.

In response, applicants elect Group I, i.e. claims 1-7, 9-12, 25-28, 48-54, drawn to adult non-transgenic multipotent human stem cells, with traverse, for initial examination. Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement for the reasons that follow.

Claims of Groups I and II Should Be Examined Together

As the Examiner conceded on page 3 of the October 20, 2005 Office Action, claim 1 is a linking claim, which links the invention of Group I and that of Group II. The Examiner also indicated that upon allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all limitations of the allowable linking claim will be entitled to examination in the instant application.

Accordingly, applicants understand that in the event claim 1 is found allowable, the invention of Group II will be examined in the subject application.

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Claims of Groups I-VII Should Be Examined Together

As the Examiner conceded on page 4 of the October 20, 2005 Office Action, the claims of Groups I/II and Groups III-VII are related as product and process of making and/or using the product. According to M.P.E.P. §821.04, "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

Accordingly, the restriction as set forth between purported Groups I-VII is improper and claims 1-54 should be examined in this application.

The Restriction Requirement Is Improper In Its Entirety

The Examiner stated that the inventions of Groups I-VII are distinct and have acquired a separate status in the art. The Examiner also stated that a different field of search would be required based upon the structurally distinct products recited and the various methods of use, and would be an undue burden on the Examiner.

Applicants respectfully disagree with the Examiner's assertion of restrictable subject matter set forth in the October 20, 2005 Office Action. Under 35 U.S.C. §121, restriction may be required if two or more "independent and distinct" inventions are claimed in one application.

Applicants maintain that the inventions of Groups I-VII are not

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independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subject matter claimed. As disclosed in the instant specification, this invention relates to novel multipotent human stem cells that can be isolated from human adipose tissue and used in therapy and cosmetology. Accordingly, applicants maintain that Groups I-VII are not independent and restriction is not proper.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction were not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the Groups III-VII, i.e. directed to methods of making and using the multipotent human stem cells of Groups I and II, would not pose a serious burden once the prior art for the claims of Groups I and II, i.e. directed to the multipotent human stem cells, has been identified. In addition, and as the Examiner conceded on pages 2-3 of the October 20, 2005 Office Action, the subject matter of Groups I-III and V-VII share the same classification.

Therefore, there is no undue burden on the Examiner to examine Groups I-VII together in the subject application. Hence,

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applicants maintain that the Examiner must examine the claims of Groups I-VII, i.e. claims 1-54, on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

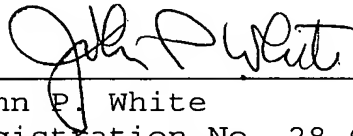
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.



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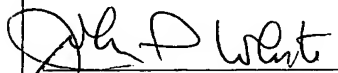
No fee, other than the enclosed \$1,020.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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